



Interagency Coordinating Committee on the Validation of Alternative Methods

A Strategic Roadmap for the Implementation of New Approaches to Safety Evaluation

Warren Casey, PhD, DABT

Director, NICEATM

NTP Interagency Center for the Evaluation of Alternative
Toxicological Methods

Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration



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Subcommittee Hearing

Hearing on FY2017 National Institutes of Health Budget Request

Labor, Health and Human Services, Education, and Related Agencies

Date: Thursday, April 7, 2016

Time: 10:00 AM

Location: Dirksen Senate Office Building 138



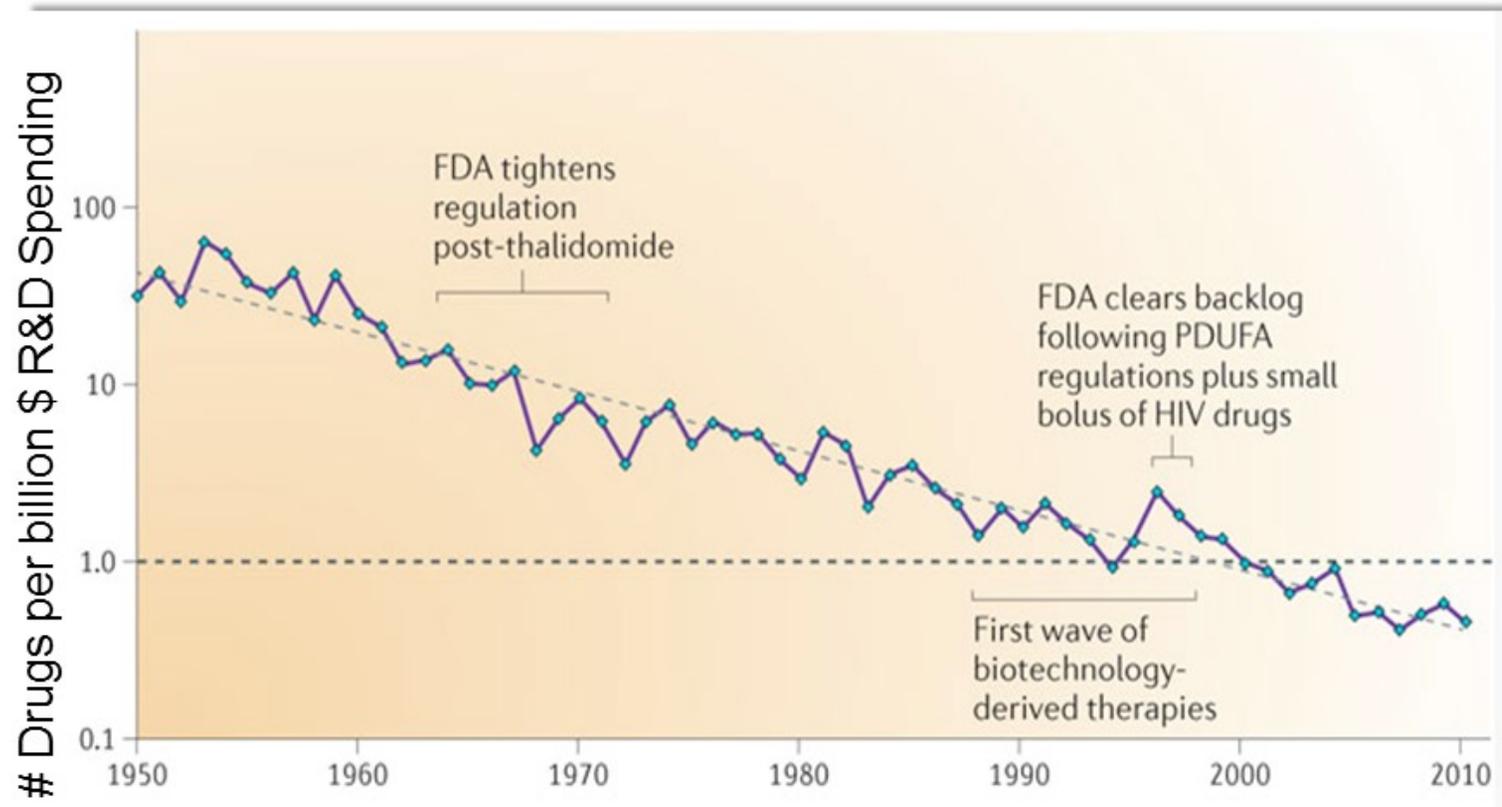
In Francis Collins' recent testimony to the congressional subcommittee with NIH budget oversight responsibility, he offered that :

“Animal safety testing for environmental chemicals and drugs will largely be replaced by tissue chips and iPS cells in 10 years.”

“.....giving results that are more accurate, at lower cost and higher throughput.”

<http://www.appropriations.senate.gov/hearings/hearing-on-fy2017-national-institutes-of-health-budget-request>

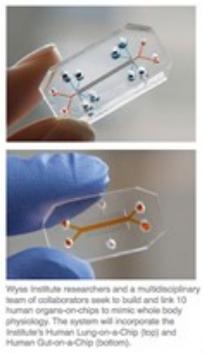
Eroom's Law



Diagnosing the decline in pharmaceutical R&D efficiency

Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington
 Nature Reviews Drug Discovery 11, 191-200 (March 2012)

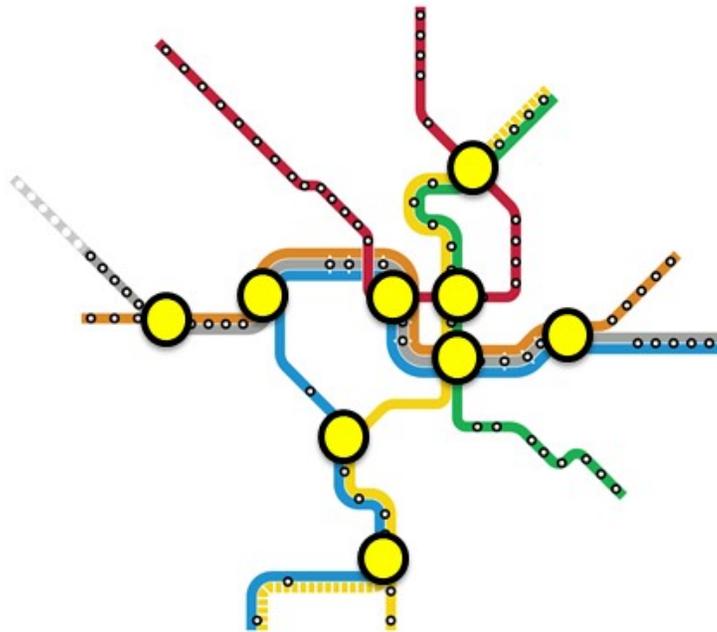
It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology



Wyss Institute researchers and a multidisciplinary team of collaborators seek to build and link 10 human organ-on-chips to mimic whole body physiology. The system will incorporate the Institute's Human Lung-on-a-Chip (top) and Human Gut-on-a-Chip (bottom).



We Need a National Roadmap



- Provides a framework to support the planning and coordination of technology development
- Helps federal agencies identify consensus goals and coordinate key activities required to achieve them
- Facilitates communication and collaboration within and between government agencies, stakeholders, and international partners



Feb 2017

- 2-day face-to-face interagency meeting to start process of establishing mission / vision / goals / objectives
- 85 participants from 16 Agencies and other interagency committees/consortia (e.g., Tox21, DoD Tri-Services Toxicology Consortium, Toxics and Risks Chemical Toxicity Assessment working group, etc...)
- Professional Facilitation





Recurrent Themes

- “The 3 C’s”
 - Communication
 - Collaboration
 - Commitment



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- Success Breeds Success
- **Transparency and Inclusivity**



Vision

To facilitate the development and use of new approaches for evaluating the safety of chemicals and medical products in the United States that will increase confidence in alternative methods and improve their relevance to human health, while maintaining a commitment to replace, reduce, and refine animal use.



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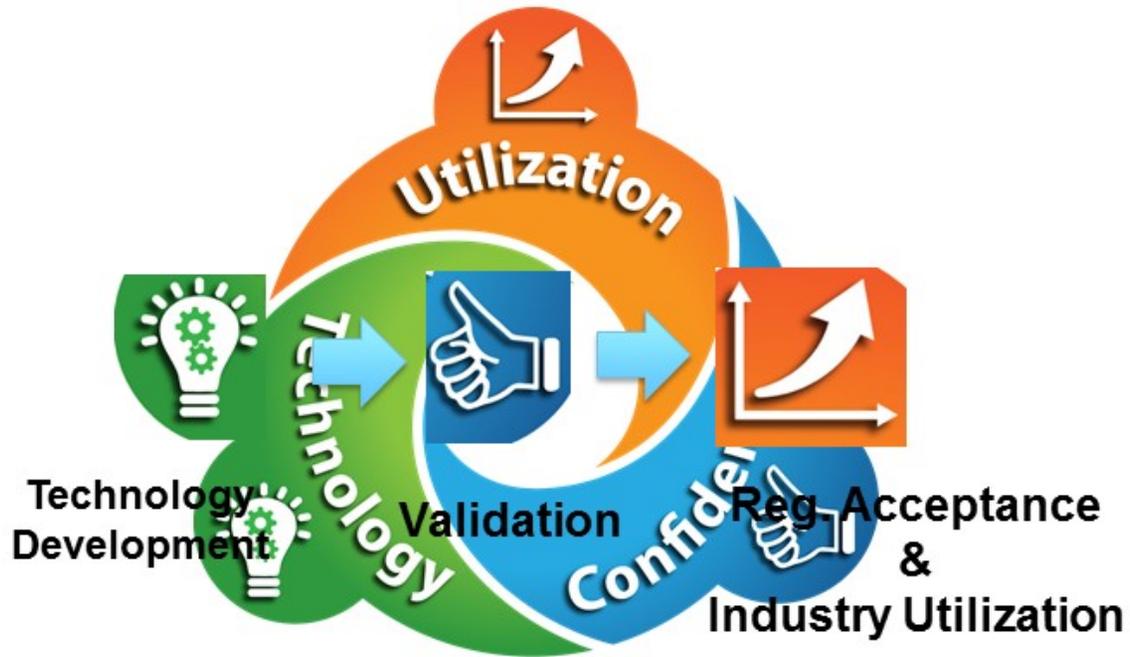
Mission

Federal agencies, the regulated community, and interested stakeholders will work together to explore new approaches for evaluating the safety of chemicals and medical products in the United States while collaborating with international partners to facilitate global harmonization of new testing approaches. The successful development and implementation of new approaches will require integrated efforts that:

- Help end-users (agencies and industry) guide the development of new tools to support regulatory and research needs
- Foster the use of timely, flexible and robust practices to establish confidence in new methods, and
- Encourage the adoption and use of new approaches by Federal agencies and regulated industries.



Start Here!





Selected Objectives

- Promote communication and data sharing across agencies and product-sectors



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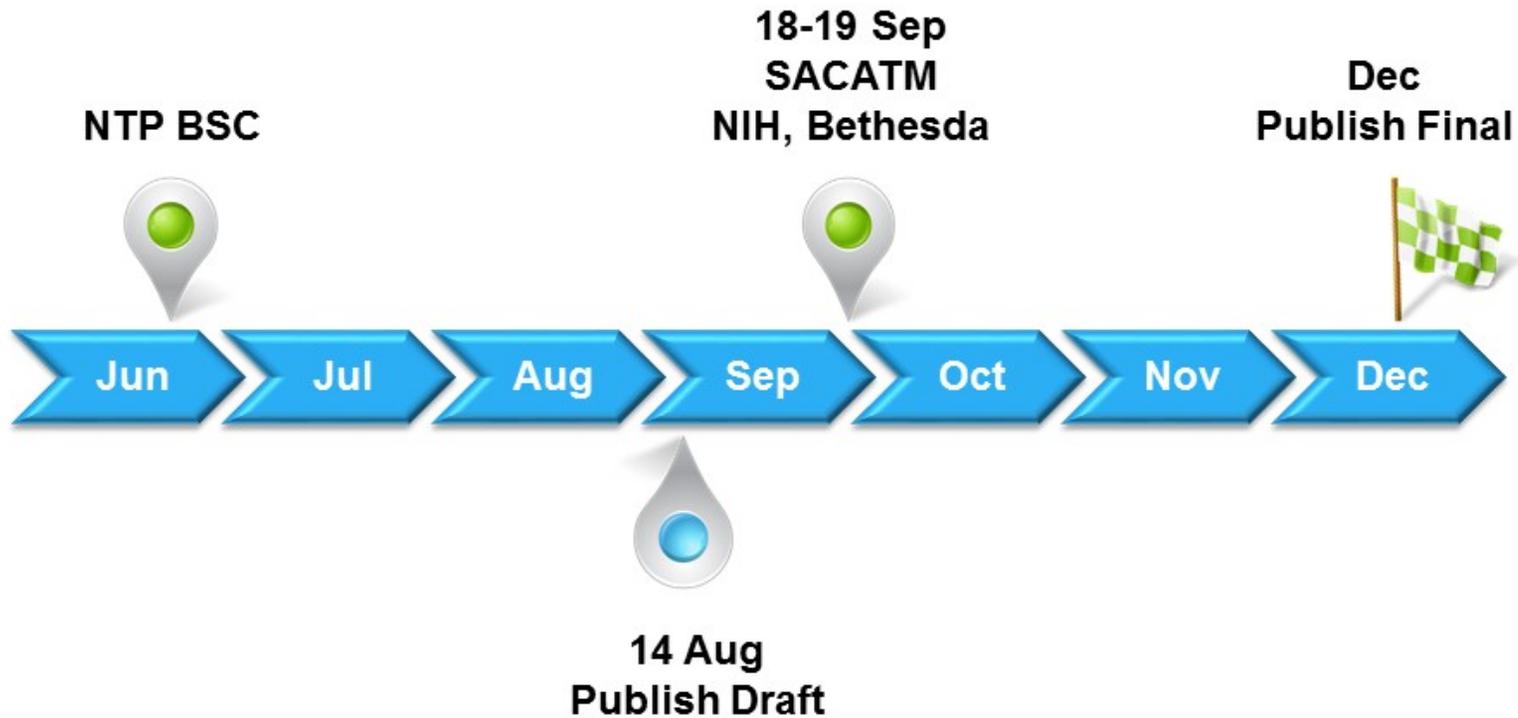


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- Promote communication and data sharing across agencies and product-sectors
- Identify / establish resources that can foster the development and utilization of new or enhanced approaches
- Develop new frameworks for establishing the scientific validity of new test methods and approaches
- Identify and utilize appropriate metrics for prioritizing activities, monitoring progress, and measuring success



Publishing the Strategic Roadmap





Implementation Plans

- Acute Toxicity
 - Oral Lethality
 - Dermal Lethality
 - Inhalation Lethality
 - Dermal Sensitization
 - Dermal Irritation / Corrosion
 - Ocular Irritation / Corrosion



Public-Private Partnerships

- Read Across
- In Vitro to In Vivo Extrapolation (IVIVE)
- DART



Comments and Suggestions



National Toxicology Program
U.S. Department of Health and Human Services

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Questions for BSC

- Please comment on the strategic roadmap's objectives as outlined in the mission as a means for achieving the safe, effective, and timely implementation of human-based, predictive approaches for toxicity testing.
- Please comment on outreach efforts that NTP might consider for engagement with key stakeholders.
- Please comment on the value of using results from animal-based testing to establish confidence in new human-based approaches